Complete if Known Substitute for form 1449/PTO 10/634,144-Conf. #5095 Application Number INFORMATION DISCLOSURE August 4, 2003 Filing Date STATEMENT BY APPLICANT First Named Inventor Jin K. Lee 1615 (Use as many sheets as necessary) G. S. Kishore Examiner Name Sheet 1 of 4 Attorney Docket Number TRA-006.01

			U.S. PA	TENT DOCUMENTS	
Examiner Initials*	Cite No.1	Document Number  Number-Kind Code <sup>2</sup> ( if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	AA*	US-4,451,447	05-29-1984	Kaplan et al.	
	AB*	US-4,590,001	05-20-1986	Stjernholm	
	AC*	US-4,767,874	08-30-1988	Shima et al.	
	AD*	US-4,889,724	12-26-1989	Kasan et al.	
	AE*	US-5,013,556	05-07-1991	Woodle et al.	
	AF*	US-5,019,369	05-28-1991	Presant et al.	
	AG*	US-5,049,388	09-17-1991	Knight et al.	
	AH*	US-5,117,022	05-26-1992	Khokhar et al.	
	AI*	US-5,320,906	06-14-1994	Eley et al.	
	AJ*	US-5,567,434	10-22-1996	Szoka, Jr.	
	AK*	US-5,616,334	04-01-1997	Janoff et al.	
	AL*	US-5,641,662	06-24-1997	Debs et al.	
	AM*	US-5,665,383	09-09-1997	Grinstaff et al.	
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	AO*	US-5,780,054	07-14-1998	Tardi et al.	
	AP*	US-5,795,589	08-18-1998	Mayer et al.	
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	AR*	US-6,147,060	11-14-2000	Zasloff et al.	
	AS*	US-6,221,388	04-24-2001	Hersch et al.	
	AT*	US-6,352,996	03-05-2002	Cao et al.	
	AU*	US-6,419,901-A1	07-16-2002	Placke et al.	
	AV*	US-6,440,393-A1	08-27-2002	Waldrep et al.	
	AW*	US-6,451,784-B1	09-17-2002	Placke et al.	
	AX*	US-6,511,676	01-28-2003	Boulikas	
	AY*	US-6,599,912	07-29-2003	Au et al.	
	AZ*	US-6,669,958	12-30-2003	Trager et al.	
	AA1*	US-6,723,338	04-20-2004	Sarris et al.	
	AB1*	US-6,726,925	04-27-2004	Needham	
	AC1*	US-6,787,132	09-07-2004	Gabizon et al.	
	AD1*	US-6,793,912-A1	09-21-2004	Pilkiewicz et al.	
	AE1*	US-6,852,334	02-08-2005	Cullis et al.	
	AF1*	US-7,025,988	04-11-2006	Zadi	
	AG1*	US-7,063,860	06-20-2006	Chancellor et al.	

Examiner	/Gollamudi Kishore/	Date	05/06/2009
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<sup>\*</sup>EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. \* CITE NO.: Those application(s) which are marked with an single asterisk (\*) next to the Cite No. are not supplied (under 37 CFR 1.98(a)(2)(iii)) because that application was filed after June 30, 2003 or is available in the IFW. ¹ Applicant's unique citation designation number (optional). ² See Kinds Codes of USPTO Patent Documents at <a href="https://www.uspto.gov">www.uspto.gov</a> or MPEP 901.04. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

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Examiner Initials*	Cite No.1	Document Number  Number-Kind Code <sup>2</sup> ( if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	AH1*	US-RE33,071	09-26-1989	Stjernholm	
	AI1*	US-2002/0009415	01-24-2002	Batich et al.	
	AJ1*	US-2002/0110586	08-15-2002	Madden et al.	
	AK1*	US-2002/0187105- A1	12-12-2002	Zou et al.	
	AL1*	US-2003/0059375- A1	03-27-2003	Perez-Soler et al.	
	AM1*	US-2003/0099718	05-29-2003	Burrell et al.	
	AN1*	US-2004/0101553	05-27-2004	Lee et al.	
	AO1*	US-2005/0074499	04-07-2005	Tagawa et al.	
	AP1*	US-2005/0207987	09-22-2005	Speirs et al.	

	FOREIGN PATENT DOCUMENTS							
Examiner	Cite	Foreign Patent Document	Publication Date	Name of Patentee or	Pages, Columns, Lines, Where Relevant Passages			
Initials*	No.1	Country Code <sup>3</sup> -Number <sup>4</sup> -Kind Code <sup>5</sup> (if known)	MM-DD-YYYY	Applicant of Cited Document	Or Relevant Figures Appear			
	ВА	JP-2001-501173	01-30-2001					
	ВВ	WO-98/07409	02-26-1998			П		
	вс	WO-98/29110	07-09-1998			П		
	BD	WO-99/15153	04-01-1999					
	BE	WO-00/27359	05-18-2000			П		
	BF	WO-03/015707	02-27-2003			П		
	ВG	WO-2004/054499	07-01-2004					
	вн	WO-2005/037341	04-28-2005			П		
	ВІ	WO-2005/089448	09-29-2005			П		

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		NON PATENT LITERATURE DOCUMENTS	
Examiner Initials	Cite No.1	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
	CA	Boulikas, T., "Low toxicity and anticancer activity of a novel liposomal cisplatin (Lipoplatin) in mouse xenografts," Oncology Reports, 12:3-12 (2004)	
	СВ	Chi et al., "Elimination of Dose Limiting Toxicities of Cisplatin, 5-Fluorouracil, and Leucovorin Using a Weekly 24-Hour Infusion Schedule for the Treatment of Patients with Nasopharyngeal Carcinoma," Cancer, 76(11):2186-2192 (1995)	
	CC	Cisplatin Injection, Drug Information Label, June 2004	
	CD	Comis, Robert L., "Carboplatin in the Treatment of Non-Small Cell Lung Cancer: A Review," Oncology, 50(Suppl 2):37-41 (1993)	
	CE	Comis, R.L., "Carboplatin in the treatment of non-small cell lung cancer: a review," Oncology, 50(2):37-41 (1993) (Abstract)	
	CF	Devarajan et al., "Low Renal Toxicity of Lipoplatin Compared to Cisplatin in Animals," Anticancer Research, 24:2193-2200 (2004)	
	CG	Embree et al., "Chromatographic Analysis and Pharmacokinetics of Liposome-Encapsulated Doxorubicin in Non-Small-Cell Lung Cancer Patients," Journal of Pharmaceutical Sciences, 82(6):627-634 (1993)	
	СН	Fujita et al., "Respiratory failure due to pulmonary lymphangitis carcinomatosis," Chest, 103(3):967-968 (1993)	
	CI	Hoffman et al., "Lung Cancer," The Lancet, 355:479-485 (2000)	
	CJ	Hojo et al., "A case of adenocarcinoma of lung cancer with multiple brain metastasis and lymphangitis carcinomatosa responding well to chemotherapy with carboplatin, etoposide and ifosfamide," Gan to Kagaku, 19(14):2403-6 (1992) Abstract	
	ск	Kinoshita, A., "Investigation of Cisplatin Inhalation Chemotherapy Effects on Mice after Air Passage Implantation of FM3A Cells," Journal of Japan Society for Cancer Therapy, 28(4):705-715 (1993)	
	CL	Knight et al., "Anti-Cancer Activity of 9-Nitrocamptothecin Liposome Aerosol in Mice," Transactions of the American Clinical and Climatological Association, Vol. III, pp 135-145 (2000)	
	СМ	Koshkina et al., "9-Nitrocamptothecin Liposome Aerosol Treatment of Melanoma and Osteosarcoma Lung Metastases in Mice," Clinical Cancer Research, 6(7):2876-2880 (2000)	
	CN	Lehninger et al., Principles of Biochemistry, Worth Publishers: New York, pp. 111-114, 134-135, 240-245, 247, 249-252, 256-259, and 262	
	со	LeighI et al., "A Phase I Study of Pegylated Liposomal Doxorubicin Hydrochloride (Caelyx™) in Combination with Cyclophosphamide and Vincristine as Second-Line Treatment of Patients with Small-Cell Lung Cancer," Clinical Lung Cancer, 5(2):107-112 (2003)	
	СР	Liams et al., "Clinical Features of Patients with Stage IIIB and IV Bronchioloaleolar Carcinoma of the Lung," Cancer, 86:1165-1173 (1999)	

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	/Gollamudi Kishore/	Date	NE/NE/2000
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<sup>&</sup>lt;sup>1</sup>Applicant's unique citation designation number (optional). <sup>2</sup>Applicant is to place a check mark here if English language Translation is attached.

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	Q	Okuyama et al., "Reinforcing Aerosol Cisplatin for Radiotherapy of Laryngeal Cancer," Tohoku Journal of Experimental Medicine, 169(3):253-255 (1993)	
	CR	Platinol®-AQ (cisplatin injection), Drug Information Label, 1999	
	cs	Poster and Oral Presentation: Chou et al., "Phase lb/IIa study of sustained release lipid inhalation targeting cisplatin by inhalation in the treatment of patients with relapsed/progressive osteosarcoma metastic to the lung," Journal of Clinical Oncology, 2007 ACSO Annual Meeting Proceedings, Part I, 25(18S)	
	СТ	Poster: Perkins et al., "An Inhalation Formulation of Liposomal Cisplatin (SLIT™Cisplatin) for Treatment of Lung Cancer," Lipids, Liposomes & Biomembranes 2005: New Technologies July 26-30, University of British Columbia, Vancouver, Canada, p. 78	
	CU	Poster: Wittgen et al., "Phase I study of aerolized SLIT cisplatin in the treatment of patients with carcinoma of the lung," Journal of Clinical Oncology, 2006 ASCO Annual Meeting Proceedings, Part I, 24(18S)	
	CV	Poster: Zou et al., "Pharmacokinetics and organ distribution of liposomal cisplatin administered intravenously and intraperitoneally," Proceedings American Association Cancer Research 2005: 45, abs LB-268	
	CW	Schwartsmann et al., "A Phase I Trial of Cisplatin Plus Decitabine, a New DNA- Hypomethylating Agent, in Patients with Advanced Solid Tumors and a Follow-Up Early Phase II Evaluation in Patients with Inoperable Non-Small Cell Lung Cancer," Investigational New Drugs, 18(1):83-91 (2000)	
	СХ	Steerenberg et al., "Liposomes as Drug Carrier System for cis-diamminedichloroplatinum (II)," Cancer Chemother. Pharmacol., 21:299-307 (1998)	
	CY	Stathopoulos et al., "Paclitaxel combined with cis-platin as second-line treatment in patients with advanced non-small cell lung cancers refractory to cis-platin," Oncology Reports, 6:797-800 (1999)	
	CZ	Stathopoulos et al., "Pharmacokinetics and adverse reactions of a new liposomal cisplatin (Lipoplatin): Phase I study," Oncology Reports, 13:589-595 (2005)	
	CA1	Vokes et al., "A Phase I Study of STEALTH Cisplatin (SPI-77) and Vinorelbine in Patients with Advanced Non-Small-Cell Lung Cancer," Clinical Lung Cancer, 2(2):128-132 (2000)	
	CB1	Wittgen et al., "Assessing a System to Capture Stray Aerosol during Inhalation of Nebulized Liposomal Cisplatin," Journal of Aerosol Medicine, 19(3):385-391 (2006)	
	CC1	Wittgen et al., "Phase I Study of Aerosolized SLIT Cisplatin in the Treatment of Patients with Carcinoma of the Lung," Clin. Cancer Res., 13(8):2414-2421 (2007)	

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